

510(k) Summary

OC1 13 2006

1. COMPANY NAME AND ADDRESS

Dutch Ophthalmic Research Center International bv
Scheijdelveweg 2
3214 VN Zuidland
The Netherlands

Contact: Mr. Ger Vijfvinkel, President

Phone : +31 181 458080

Fax : +31 181 458090

Date of summary: September 15, 2006

2. DEVICE NAME

Trade Name : Xenon BrightStar Illumination System
Common Name : Ophthalmic Light Source
Classification Name : Endoilluminator (21 CFR 876.1500,
Product Code MPA, GCT)

3. PREDICATE DEVICE

D.O.R.C. HEXON ILLUMINATION SYSTEM (K973229)

4. DEVICE DESCRIPTION

The Xenon BrightStar Illumination System consists of the Illumination Unit and accessories. The Illumination Unit uses a Xenon Short Arc Lamp and utilizes two internal focusing systems to focus the light into the end of an optical fiber of two individually controlled ports. Both ports can be individually controlled by choice of an UV cut-off filter and a light intensity setting. Accessories to the system include single use and reusable fiber optic probes, fibers and micro instruments which are delivered sterile or require sterilization prior to use.

5. INTENDED USE

The Xenon BrightStar Illumination System is intended to provide intraocular illumination in vitreoretinal surgery.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The following table summarizes the technological characteristics of the Xenon BrightStar Illumination System in comparison to the predicate D.O.R.C. Hexon Illumination System.

Comparison of Xenon BrightStar Illumination System to Predicate Device			
		Xenon BrightStar	D.O.R.C. Hexon
Characteristic		Illum. System	Illum. System
		1266.XIII	1266.XII
Indication: Endoillumination for vitreoretinal surgery		YES	YES
Lamp Type		Xenon Short Arc	Metal Halide
Lamp rating (Watts)		75	24
Light Output (lumens)		Min. 850	1850
Color Temperature (degrees K)		Approx. 6000	4700
Variable intensity		YES	YES
Intensity displayed		YES	NO
Wavelength Range (nm)		410-700	400-800
UV filtration (nm)	420	YES	NO
	435	YES	YES
	475	YES	YES
	515	YES	NO
Infrared filtration		YES	YES
Additional color filtration		NO	YES
Sterilizable knobs		YES	NO
Multiple probe diameters		YES	YES
Panoramic light probes		YES	YES
Straight Probes		YES	YES
Illuminated accessories		YES	YES
Illumination ports		2	1
Dimensions of unit (mm)		350 x 250 x 300	150 x 257 x 256
Weight of unit (kgs)		15	6



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dutch Ophthalmic Research Center International
c/o Ms. Fran Carleton
One Little River Rd.
Kingston, NH 03848

OCT 13 2006

Re: K062895

Trade/Device Name: Xenon BrightStar Illumination System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoilluminator
Regulatory Class: Class II
Product Code: MPA
Dated: September 25, 2006
Received: September 27, 2006

Dear Ms. Carleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "MB Eydelman, M.D.", written in a cursive style.

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose
and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062895

Device Name: XENON BRIGHTSTAR ILLUMINATION SYSTEM

Indications for Use:

The Xenon BrightStar Illumination System is intended to provide intraocular illumination in vitreoretinal surgery.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dennis L. Mc Carthy
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K062895